K102490

JUN - 2 2011

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date Prepared:	April 7, 2011
Trade Name:	IgX PLEX™ Celiac Qualitative Assay
Common Name:	Integrated system for the qualitative detection of IgA and IgG class of anti-tissue transglutaminase in serum samples
Classification:	Class II
Product Code:	MVM-866.5660: Autoantibodies, Endomysial (Tissue Transglutaminase)
Substantial Equivalence:	Aesku, Inc.- Aeskulisa tTG A and tTG G (K042644)

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Intended Use

The IgX PLEX™ Celiac Qualitative Assay is an in vitro diagnostic test for the qualitative detection of the IgA and IgG immunoglobulin classes of anti-tissue transglutaminase antibody in serum. The test is intended for use in clinical laboratories as an aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings, and requires the SQiDworks™ Diagnostics Platform.

Device Description

The IgX PLEX™ Celiac Qualitative Assay is a consumable reagent kit. It is designed to run on the SQiDworks™ Diagnostics Platform. The kit includes a Microarray Plate, Reporter mix, standards, controls, sample diluents, wash buffer concentrates and a CD-ROM.

The Assay Kit detects the presences of the IgA and IgG classes of anti-tissue transglutaminase antibody. This is performed in an integrated fashion on the SQiDworks™ Diagnostics Platform (platform) that reports both analytes simultaneously to aid in the diagnosis of Celiac Disease.

The platform automates the entire immunoassay procedure from end-to-end, including calibrator/standards and sample pipetting, sample dilution, incubation, washing, and drying. Once the assay's biochemical reactions have completed, the instrument automatically performs a multi-color fluorescent scan of each well in the microarray, analyzes the data, and generates a report containing qualitative results for both assay markers. Results for each patient sample from the IgX PLEX™ Celiac Qualitative assay are obtained simultaneously for each of the two markers using the results from one well containing one aliquot of the patient's serum. Results are reported independently.

Comparison to Predicates

The IgX PLEX™ Celiac Qualitative Assay uses the same ELISA assay principles of capture antigen, sample addition/incubation, reporter addition/incubation and fluorescent signal interpretation as the predicates with the improvements of using an automated system and multiplexing immunoassay. The intended use of the IgX PLEX™ Celiac Qualitative Assay and its predicates are equivalent, to aid in the diagnosis of Celiac Disease.

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Test Studies

A series of test studies were conducted in support of the comparability, safety and effectiveness of the IgX PLEX™ Celiac Qualitative Study and its predicates. The studies completed with the results as follows:

- Reproducibility ranges were 92.4% to 100% for anti-tTG-IgA and 95.8%-100% for anti-tTG-IgG.
- Clinical sensitivity was 98.3% for anti-tTG-IgA and 80.9% for anti-tTG-IgG. Clinical specificity was 94.5% for anti-tTG-IgA and 89.0% for anti-tTG-IgG.
- Overall agreement between the analytes in the IgX PLEX™ Celiac Qualitative Assay and established predicate test systems was 89.3% for anti-tTG-IgA and 85.1% for anti-tTG-IgG.
- None of the analytes in the assay were affected by high levels of the following biological substances: bilirubin, hemoglobin, triglycerides and human IgG.

Conclusion

In conclusion, the IgX PLEX™ Celiac Qualitative Assay demonstrated performance, safety and effectiveness equivalent or superior to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SQI Diagnostics Systems Inc.
c/o Dr. Kate Smith
Vice President, Regulatory Affairs
36 Meteor Drive
Toronto, Ontario, Canada M9W 1A4

JUN 0 2 2011

Re: k102490
Trade/Device Name: IgX PLEX™ Celiac Qualitative Assay
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MVM
Dated: May 27, 2011
Received: May 31, 2011

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Leena Philip

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102490

Device Name: IgX PLEX™ Celiac Qualitative Assay

Indications For Use:

The IgX PLEX™ Celiac Qualitative Assay is an in vitro diagnostic test for the qualitative detection of the IgA and IgG immunoglobulin classes of anti-tissue transglutaminase antibody in serum. The test is intended for use in clinical laboratories as an aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings, and requires the SQiDworks™ Diagnostics Platform.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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